

were class members at the time of the approval of the class action settlement and continue to be so even though they now have separate lawsuits pending.

There are 485 plaintiffs in these five actions, and they are all represented by the same counsel.<sup>4</sup> Their motions for remand are before the undersigned as the transferee judge in MDL 1203, the mass tort litigation involving Wyeth's diet drugs commonly known as fen-phen. No federal claim for relief is alleged. Because these motions present nearly identical legal and factual issues, we will address them together.

1.

In brief summary, plaintiffs, all of whom are citizens of Mississippi, filed suits for injuries sustained as a result of their use of the diet drugs known as Pondimin and/or Redux. The defendant Wyeth, the manufacturer of Pondimin and Redux, is a party of diverse citizenship from the plaintiffs. The defendant physicians who prescribed Pondimin and/or Redux to plaintiffs and the various in-state pharmacies that filled plaintiffs' prescriptions are alleged to be citizens of Mississippi.

Plaintiffs originally filed their complaints in various Mississippi Circuit Courts in September or December, 2002, more than five years after fen-phen was withdrawn from the market in September, 1997. Specifically, plaintiffs in Ramsey filed their complaint in December, 2002, while the remaining actions were

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4. Some plaintiffs are derivative claimants suing for loss of consortium.

filed in September, 2002. Wyeth timely removed the actions. The federal courts in Mississippi deferred ruling on plaintiffs' motions, and the cases were then transferred to this court as part of MDL 1203.

The plaintiffs maintain that remand is appropriate because complete diversity does not exist as required under 28 U.S.C. § 1332(a). Wyeth counters that the non-diverse physicians were fraudulently joined because the applicable two-year statute of limitations bars plaintiffs' claims against these non-diverse defendants.<sup>5</sup> See MISS. CODE ANN. § 15-1-36 (West 2003). Thus, Wyeth argues, plaintiffs' claims against these non-diverse defendants should be disregarded for purposes of determining diversity of citizenship of the parties. Wyeth also argues that the in-state pharmacies are fraudulently joined because Mississippi law precludes claims against a pharmacy for properly filling a prescription. Plaintiffs respond that the statute of limitations has not expired because they discovered their injuries less than two years prior to filing their complaints against the non-diverse defendants. With respect to the pharmacy defendants named in the Ramsey action, plaintiffs assert that strict liability claims are allowed against them as sellers under Mississippi law.

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5. The statute of limitations is not an issue in plaintiffs' claims against Wyeth, which has waived its right to assert the statute of limitations defense in return for the plaintiffs giving up their right to sue Wyeth for "punitive, exemplary, or multiple damages." Settlement Agreement § IV.D.3.c; see PTO No. 2625 and PTO No. 2680.

## II.

This court addressed similar issues presented by plaintiffs' remand motions in PTO No. 3281 in French, et al. v. Wyeth, et al., CIV.A. No. 03-20353 (E.D. Pa. Feb. 18, 2004), which is also part of the nationwide diet drug litigation. In French, we laid out in detail the standards for removal based on diversity jurisdiction and fraudulent joinder. See PTO No. 3281 at 2-4. We also discussed at length the issue of when plaintiffs reasonably could have known about their alleged injuries as it relates to the Mississippi statute of limitations. See id. at 5-13. Because we examined the same legal issues as they applied to nearly identical facts in French, we need not revisit them here.

## III.

We first turn to the issue of whether the prescribing physicians, all purportedly Mississippi citizens, were fraudulently joined as defendants for the purpose of destroying diversity of citizenship and preventing removal, the same issue we examined more fully in French. Plaintiffs have brought claims for medical negligence against all of these non-diverse defendants.

Wyeth argues that plaintiffs' complaints do not state colorable claims against these defendants because plaintiffs' claims are barred by the Mississippi statute of limitations. The statute provides in relevant part:

For any claim accruing on or before June 30, 1998, and except as otherwise provided in this section, no claim in tort may be brought against a licensed physician, osteopath,

dentist, hospital, institution for the aged or infirm, nurse, pharmacist, podiatrist, optometrist or chiropractor for injuries or wrongful death arising out of the course of medical, surgical or other professional services unless it is filed within two (2) years from the date the alleged act, omission or neglect shall or with reasonable diligence might have been first known or discovered.

MISS. CODE ANN. § 15-1-36(1) (emphasis added). For any claim accruing on or after July 1, 1998, the statute of limitations is the same for all relevant purposes.<sup>6</sup>

#### IV.

As set forth in greater detail in French, there was massive publicity, both locally and nationally, from 1997 through March of 2000 concerning Wyeth's diet drugs and their connection to valvular heart disease. As we stated in French, in light of this massive publicity, plaintiffs, if they had acted with reasonable diligence, should have had knowledge of their alleged injuries by the end of March, 2000. We thus find that plaintiffs' actions accrued under the Mississippi statute of limitations no later than this time. See Fortenberry v. Mem'l Hosp. at Gulfport, Inc., 676 So.2d 252, 255 (Miss. 1996); see also First Trust Nat'l Ass'n v. First Nat'l Bank of Commerce, 220 F.3d 331, 336-37 (5th Cir. 2000); In re Catfish Antitrust Litig., 826 F. Supp. 1019, 1031 (N.D. Miss. 1993). Since

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6. The statute of limitations for claims accruing after July 1, 1998 adds tolling provisions for fraudulent concealment and instances when a foreign object is left in a patient's body. See MISS. CODE ANN. § 15-1-36(2)(a),(b). Both provisions require a plaintiff to bring an action within two years of the time when the alleged injury or fraud should have been discovered, and no later than seven years after the alleged act of neglect. See id.

plaintiffs did not file their actions until September and December, 2002 their claims of negligence against the in-state physicians are time barred.

Accordingly, for the reasons more fully articulated in French, we find that Wyeth has met its heavy burden of showing that the in-state physician defendants are fraudulently joined.

v.

Plaintiffs in the Ramsey action also bring claims in negligence and strict liability against the in-state pharmacies that allegedly filled their prescriptions for Pondimin and/or Redux. Wyeth contends that these defendants are fraudulently joined because Mississippi law precludes claims against a pharmacy for properly filling a prescription. In Moore v. Mem'l Hosp. of Gulfport, 825 So.2d 658 (Miss. 2002), the Supreme Court of Mississippi held that the learned intermediary doctrine applies to "pharmacists and that pharmacists owe no legal duty to warn in the context of prescription medication." Id. at 664-65. The court carved out two exceptions to the doctrine: "where it was undisputed that a plaintiff had informed the pharmacy of health problems which contraindicated the use of the drug in question," and "where pharmacists fill prescriptions in quantities inconsistent with the recommended dosage guidelines." Id. at 665.

Plaintiffs do not allege that they told the pharmacies of an outstanding medical condition which would preclude the prescription of diet drugs or that the pharmacy defendants filled

their prescriptions outside of the recommended dosage guidelines. Plaintiffs instead argue that their strict liability claims against the pharmacy defendants are not precluded by Moore because Moore applies only to negligence claims. We disagree.

The Mississippi Supreme Court in Bennet v. Madakasira, 821 So.2d 794, 804 (Miss. 2002), found that strict liability and negligence principles "merge into one inquiry; the adequacy of defendant's warnings." Id. (quoting Swayze v. McNeil Labs., Inc., 807 F.2d 464, 467 (5th Cir. 1987)). Because pharmacists have no duty to warn under Moore except in limited circumstances that do not apply here, it necessarily follows that plaintiffs' claims against the pharmacies must fail.

In light of the above analysis, as well as the thorough and well reasoned analysis of the same issue in In re Rezulin Prods. Liab. Litig., 133 F. Supp. 2d 272, 288-90 (S.D.N.Y. 2001), we conclude that there is no "reasonable basis in fact" supporting the Ramsey plaintiffs' claims against the pharmacy defendants under Mississippi law. See Boyer v. Snap-On Tools, Inc., 913 F.2d 108, 111 (3d Cir. 1990). Thus, we find that the defendant pharmacies are fraudulently joined.

Vl.

For the same reasons articulated in French concerning in-state physicians and those articulated above regarding the in-state pharmacy defendants, Wyeth has met its heavy burden of showing that these defendants are fraudulently joined. Accordingly, we will deny the motions of the plaintiffs to remand

these actions to the several Mississippi state courts and will dismiss the complaints as to these physicians and pharmacies.<sup>7</sup>

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7. We are only dismissing claims against those defendant physicians and pharmacies which appear on the MDL 1203 docket in these actions. The plaintiffs' original complaints filed in the several Mississippi state courts named as defendants additional physicians and pharmacies not before this court.

MAR-08-2004 16:21

US DISTRICT COURT EDPA

P.15/19

IN THE UNITED STATES DISTRICT COURT  
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: DIET DRUGS (Phentermine/ Fenfluramine/Dexfenfluramine) PRODUCTS LIABILITY LITIGATION	:	MDL DOCKET NO. 1203
THIS DOCUMENT RELATES TO:	:	
ELSIE D. JAMISON	:	CIVIL ACTION NO. 03-20317
v.	:	
WYETH, et al.	:	
SHIRLEY R. JOBE, et al.	:	CIVIL ACTION NO. 03-20232
v.	:	
WYETH, et al.	:	
KATHY MORTON	:	CIVIL ACTION NO. 03-20127
v.	:	
WYETH, et al.	:	
JEAN G. RAMSEY, et al.	:	CIVIL ACTION NO. 03-20344
v.	:	
WYETH, et al.	:	
JENNIFER STIMAGE, et al.	:	CIVIL ACTION NO. 03-20230
v.	:	
WYETH, et al.	:	

PRETRIAL ORDER NO. 333

AND NOW, this 5th day of March, 2004, for the reasons set forth in the accompanying Memorandum, it is hereby ORDERED that:

(1) the motion of plaintiff Elsie D. Jamison in Elsie D. Jamison v. Wyeth, et al., CIV.A. No. 03-20317 (E.D. Pa.) to remand to the Circuit Court of Claiborne County, Mississippi is DENIED;

(2) all claims in Jamison against defendant Roy Maxwell Barnes, M.D. are DISMISSED;

(3) the motion of plaintiffs in Shirley R. Jobe, et al. v. Wyeth, et al., CIV.A. No. 03-20232 (E.D. Pa.) to remand to the Circuit Court of Holmes County, Mississippi is DENIED;

(4) all claims in Jobe against defendants S.D. Austin, M.D., Frank R. Banks, M.D., John Russell Barnes, M.D., L.J.P. Bell, Jr., M.D., William G. Bennett, M.D., Brett O. Brown, M.D., Mona M. Castle, M.D., George L. Cain, Jr., M.D., Richard S. Clark, M.D., Billy T. Collum, M.D., Robert F. Cooper, M.D., Richard H. Corson, M.D., Samuel J. Creekmore, III, M.D., Norris V. Crump, M.D., Laurence L. Dennis, II, M.D., John G. Downer, M.D., David Dunn, M.D., John D. Dyer, M.D., Guy R. Farmer, M.D., Dorothy Gillespie, M.D., Richard M. Glasgow, M.D., Edward K. Gore, M.D., Walter C. Gough, M.D., Charles J. Gruich, M.D., Eric Harding, M.D., Michael Havens, M.D., Richard G. Hendrick, III, M.D., Woodie D. Harron, M.D., L.G. Hopkins, M.D., James E. Hubbard, Jr., M.D., Dwight A. Johnson, M.D., R. Barry Jones, M.D., Samuel Kumah, M.D., B.L. Lambert, M.D., Lucius M. Lampton, M.D., Zina D. Lee, M.D., John R. Lovelace, M.D., William L. Marcy, M.D., S. Jay McDuffie, M.D., Cooper A. McIntosh, M.D., John W. McFadden, Jr., M.D., Patrick G. McLain, M.D., Alfred E. McNair, M.D., Charles D. Miles, M.D., V. Arthur Miller, M.D., Richard D. Miller, M.D., Sharon B. Mitchell, M.D., Brooks V. Monaghan, Jr., M.D., J.D. Moore, M.D., Troy D. Morris, M.D., Eugene M. Murphey, III, M.D., F. Lee Neal, Jr., M.D., D.W. Norris, M.D., Anthony Pagliarulo, M.D., George D. Pollock, M.D., Robert E. Ray, M.D., Subbulaxmi Rayudu, M.D., Aney J. Reese,

D.O., Geza Remak, M.D., Joseph F. Roberts, M.D., Curren J. Sanders; M.D., Thomas Sheffield, M.D., Stephen M. Shirley, M.D., L. Edsel Stewart, M.D., Eugene C. Stone, Jr., M.D., Deborah D. Sumrall, M.D., William Sutherland, M.D., Tim Thompson, M.D., Maria V. Valdez, M.D., Rosie Walker-McNair, M.D., Willie Lee Wells, M.D., Harold J. Wheeler, M.D., Kenneth Williams, M.D., and William Yoe, M.D. are DISMISSED;

(5) the motion of defendant John D. Dyer, M.D. in Jobe to dismiss (Doc. #2) is DENIED as moot;

(6) the motion of plaintiff Kathy Morton in Kathy Morton v. Wyeth, et al., CIV.A. No. 03-20127 (E.D. Pa.) to remand to the Circuit Court of Lee County, Mississippi is DENIED;

(7) all claims in Morton against James H. Neely, M.D. are DISMISSED;

(8) the motion of plaintiffs in Jean G. Ramsey, et al. v. Wyeth, et al., CIV.A. No. 03-20344 (E.D. Pa.) to remand to the Circuit Court of Hinds County, Mississippi is DENIED;

(9) all claims in Ramsey against Frank R. Banks, M.D., Julian A. Brown, Jr., M.D., Francisco Camero, M.D., Mona M. Castle, M.D., Vernon A. Chase, M.D., Bertin C. Chevis, M.D., Charles Crenshaw, III, M.D., A. Dean Cromartie, Charles F. Elliott, Guy R. Farmer, Sr., M.D., Olawale O. Fashina, M.D., Edward K. Gore, M.D., Brooks Griffin, J. Brooks Griffin, M.D., Woodie D. Herron, M.D., Lloyd G. Hopkins, William G. Jackson, M.D., R. Barry Jones, M.D., B. Lewayne Lambert, M.D., Ramon C. Lott, M.D., S. Jay McDuffie, M.D., John R. Mitchell, M.D., Troy

D. Morris, M.D., Louis J. Owens, M.D., E.J. Price, Subbulaxmi Rayudu, Richard H. Russell, Curren J. Sanders, M.D., C.R. Secrest, M.D., Stephen M. Shirley, M.D., Larry W. Sivils, M.D., Dwalia S. South, M.D., Grayden A. Tubb, M.D., William M. Wadsworth, M.D., Clinton L. Washington, M.D., Willie L. Wells, James P. Wood, M.D., and Benjamin O.W. Yarbrough, M.D. are DISMISSED;

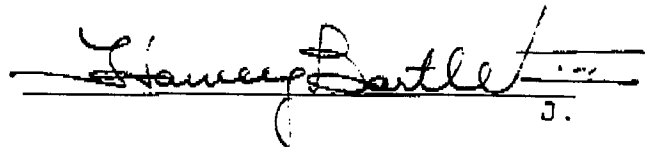
(10) all claims in Ramsey against Ashland Discount Drugs, Booneville Discount Drugs, Chandler Drugs, Inc., Coldwater Pharmacy, DeSoto Discount Drugs, Drug Stores, Eastside Pharmacy, Familymeds Pharmacy, #812, Freeman Pharmacy, G&M Pharmacy, Griffins Discount Pharmacy, Inc., Hamilton Pharmacy, Hoover's Drug Store, Inc., Houston Discount Pharmacy, Inc., Iuka Discount Drugs, Jim Bain's Pharmacy, King's Discount Drugs, Inc., Lab Discount Drugs, Liberty Drug Store, Magnolia Discount Drugs, Inc., May's Pharmacy, Inc., McDuffie Pharmacy, Medical Arts Pharmacy, Medical Center Pharmacy, Medical Plaza Pharmacy, Medicap Pharmacy, Mette Save Discount Drug, Mississippi Discount Drugs, Inc., Moore Discount Drugs, Petal Drug Co., Pontotoc Hospital & Nursing Home, Prescription Center, Sav-On-Drugs, Sverex Drugs, Stepp-Saver Pharmacy, Sullivan's Drug Store, and Super Sav-On-Drugs are DISMISSED;

(11) the motion of defendant Drug Stores to dismiss in Ramsey (Doc. #9) is DENIED as moot;

(12) the motion of plaintiffs in Jennifer Stimage, et al. v. Wyeth, et al., CIV.A. No. 03-20230 (E.D. Pa.) to remand to the Circuit Court of Hinds County, Mississippi is DENIED; and

(13) all claims in Stimage against Clifton C. Cartwright, Mona M. Castle, Richard S. Clark, Robert F. Cooper, III, Richard H. Corson, II, Norris V. Crump, Laurence L. Dennis, II, Samuel W. Fillingane, Richard M. Glasgow, Edward K. Gore, Scott A. Hall, Woodie D. Herron, James Holzhauer, M.D., L.G. Hopkins, M.D., Michael G. Howell, James E. Hubbard, William F. Krooss, B.L. Lambert, Lucius M. Lampton, William E. Loper, III, S. Jay McDuffie, Patrick G. McLain, V. Arthur Miller, Sharon B. Mitchell, Louis J. Owens, Terry B. Parsons, Rex B. Perkins, Jr., James D. Polk, Robert E. Ray, Sreedhar Rao Rayudu, Subbulaxmi Rayudu, David S. Richardson, Stephen M. Shirley, Donald Smith, L. Edsel Stewart, Grayden A. Tubb, Harold J. Wheeler, and William G. Mumm, M.D. are DISMISSED.

BY THE COURT:

  
J.



# **EXHIBIT 9**

IN THE UNITED STATES DISTRICT COURT  
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

_____	)	
IN RE DIET DRUGS	)	
(PHENTERMINE/FENFLURAMINE/	)	MDL NO. 1203
DEXFENFLURAMINE) PRODUCTS	)	
LIABILITY LITIGATION	)	
_____	)	
THIS DOCUMENT RELATES TO:	)	
ALL ACTIONS	)	
_____	)	
SHEILA BROWN, et al. v. AMERICAN	)	CIVIL ACTION NO. 99-20593
HOME PRODUCTS CORPORATION	)	
_____	)	

NATIONWIDE CLASS ACTION  
SETTLEMENT AGREEMENT WITH  
AMERICAN HOME PRODUCTS CORPORATION  
(AS AMENDED)

Dated: November 18, 1999

Amended: November 24, 1999 (First Amendment)  
January 10, 2000 (Second Amendment)  
March 24, 2000 (Third Amendment)  
July 20, 2000 (Fourth Amendment)  
November 21, 2002 (Fifth Amendment)  
January 10, 2003 (Sixth Amendment)

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# NATIONWIDE CLASS ACTION SETTLEMENT AGREEMENT WITH AMERICAN HOME PRODUCTS CORPORATION

## PREAMBLE

American Home Products Corporation ("AHP") and the undersigned representatives of the purported class and subclasses defined herein (the "Class Representatives") (together, the "Parties") hereby agree to propose a nationwide Class Action Settlement which would resolve, on the terms set forth in this Settlement Agreement, "Settled Claims" against AHP and other "Released Parties" arising from the marketing, sale, distribution and use of the diet drugs Pondimin<sup>®</sup> and Redux<sup>™</sup>, pending in various courts, including but not limited to claims which have been made in the actions that have been transferred for coordinated or consolidated pretrial proceedings to the United States District Court for the Eastern District of Pennsylvania under Docket No. MDL 1203 (the "Federal District Court"), in *Vadino et al. v. AHP* (Docket No. MID-L-425-98), and in the numerous other State Courts around the United States. The Parties to this Agreement are aware of the following certified or conditionally certified nationwide or statewide classes involving Pondimin<sup>®</sup> and Redux<sup>™</sup> as of October 7, 1999: United States District Court for the Eastern District of Pennsylvania, *Jeffers v. American Home Products Corp.*, C.A. No. 98-CV-20626 (E.D. Pa.) (*In re Diet Drug Products Liability Litigation*, MDL 1203) (nationwide medical monitoring class); West Virginia (*Burch et al. v. AHP*, Civil Action No. 97-C-204(1-11)) (statewide personal injury and medical monitoring class); Illinois (*Rhyne v. AHP*, 98 CH 4099) (statewide refund and monitoring reimbursement class); New Jersey (*Vadino et al. v. AHP*, Docket No. MID-L-425-98) (statewide Unfair and Deceptive Acts and Practices and medical monitoring class); New York (*New York Diet Drug Litigation*, Index No. 700000/98) (statewide medical monitoring class); Pennsylvania (*Pennsylvania Diet Drug Litigation*, Master Docket No. 9709-3162 C.C.P. Phila.) (statewide medical monitoring class); Texas (*Earthman v. AHP*, No. 97-10-03970 CV, Dist. Ct. Montgomery Co. Texas) (statewide medical monitoring class); and Washington (*St. John v. AHP*, 97-2-06368-4) (statewide medical monitoring class).

This Settlement Agreement shall not be construed as evidence of or as an admission by AHP of any liability or wrongdoing whatsoever or as an admission by the Class Representatives or members of the Settlement Class as defined herein ("Class Members") of any lack of merit in their claims.

Accordingly, AHP and the Class Representatives hereby agree, subject to Final Judicial Approval (except as to the Accelerated Implementation Option ("AIO") described in Section V below), compliance with applicable legal requirements, and other conditions, all as set forth below, that Fund A and Fund B shall be established, from which the benefits described herein will be paid to the Class Members of the proposed Settlement Class and Subclasses, and that the Settled Claims against AHP and other Released Parties, as defined herein, will be settled, compromised and released, in accordance with the following terms.

## I. DEFINITIONS

For purposes of this Settlement Agreement the following terms (designated by initial capitalization throughout this Agreement) shall have the meanings set forth in this Section. Terms used in the singular shall be deemed to include the plural and vice versa.

1. "Adjusted Maximum Available Fund B Amount" shall mean the amount determined by adding the Fund A Transfer Amount to the Maximum Available Fund B Amount as defined in this Section, and by then subtracting from the resulting sum all amounts paid by the Trust out of the Fund A Transfer Amount for any purpose. The "Maximum Available Fund B Amount" shall mean the amount determined by adding \$2,550,000,000 and the Fund B Accretions and by then subtracting from the resulting sum: (i) the Fund B Initial Payment under Section III.C.2; (ii) all amounts paid or transferred by AHP to the Trustees for deposit into Fund B or the Settlement Fund pursuant to Fund B Quarterly Notices under Section III.C.3, pursuant to Requests for Fund B AIO Payments under Section V.F.2, or pursuant to other payment or deposit requests from the Trust for deposits into Fund B; and (iii) Credits to which AHP is entitled under Section VII.A (Opt-Out Credits) and Section VII.C.1.g (Cross-Claim Credits), provided that Initial Opt-Out Credits (as defined in Section VII.A.2) and Back-End Opt-Out Credits (as defined in Section VII.A.3) shall be applied to reduce the Maximum Available Fund B Amount only when and as provided in Section VII.A. "Fund B Accretions" shall be determined as follows: On the first day of the first AIO Fiscal Quarter or Fiscal Quarter (whichever is applicable) after the Final Judicial Approval Date or the date on which it is determined that Final Judicial Approval will not be obtained, the Trustees shall calculate a quarterly accretion to the Maximum Available Fund B Amount which will be one and one-half percent (1.5%) of the Maximum Available Fund B Amount determined as of the close of the preceding AIO Fiscal Quarter or Fiscal Quarter, whichever is applicable. Such accretions shall be added to the Maximum Available Fund B Amount as of the day on which the accretion is calculated.
2. "Administrative Reserve" has the meaning provided in Section III.C.3.b.
3. [This section intentionally left blank.]
4. "AHP" means American Home Products Corporation, its successors and assigns.
5. "AHP Released Parties" shall mean the Released Parties described in Sections I.48.a and I.48.b herein.

6. "AIO Fiscal Year" shall mean the partial calendar year and each calendar year after the date on which it is finally determined that Final Judicial Approval will not be obtained or the Settlement Agreement is otherwise terminated, as follows. The first AIO Fiscal Year shall be the partial calendar year beginning on the date on which it is determined that Final Judicial Approval will not be obtained or the Settlement Agreement is otherwise terminated. The second AIO Fiscal Year shall be the calendar year beginning on the first day of the year following the year in which Final Judicial Approval is not obtained or the Settlement Agreement is otherwise terminated, and so forth. "AIO Fiscal Quarter" shall mean the partial calendar quarter and each calendar quarter after the date on which it is finally determined that Final Judicial Approval will not be obtained or the Settlement Agreement is otherwise terminated, as follows. The first AIO Fiscal Quarter shall be the partial calendar quarter beginning on the date on which it is determined that Final Judicial Approval will not be obtained or the Settlement Agreement is otherwise terminated. The second AIO Fiscal Quarter shall be the calendar quarter beginning on the first day of the calendar quarter following the quarter in which Final Judicial Approval is not obtained or the Settlement Agreement is otherwise terminated, and so forth.
7. "AIO Start Date" shall mean the date on which the Trial Court determines by oral or written decision whether or not to approve the Settlement or the date on which AHP terminates the Settlement Agreement, whichever is earlier.
8. "Business Day" shall mean any day other than Saturday, Sunday or New Year's Day, Birthday of Martin Luther King, Jr., Washington's Birthday, Memorial Day, Independence Day, Labor Day, Columbus Day, Veterans Day, Thanksgiving Day, Christmas Day, and any other day appointed as a holiday by the President or the Congress of the United States.
9. "Claim for Benefits" or "Claim for Settlement Benefits" or "Claim" refers to the submission of a form in which a Class Member elects the Accelerated Implementation Option (or "AIO"), or the submission of a form in which a Class Member seeks to register for any of the benefits available to Class Members pursuant to this Settlement Agreement, or the submission of a form through which a Class Member seeks Matrix Compensation Benefits pursuant to the matrices, along with all other materials including correspondence, documents and video tapes or disks of Echocardiograms submitted with such forms or in support of such a Claim.
10. "Class Counsel" shall mean those attorneys executing this Settlement Agreement on behalf of the Class Representatives, or such other attorneys as shall be approved by the Court as counsel to the Settlement Class.

11. "Claims Administrator" shall mean any person or persons to be appointed by the Trustees, subject to approval of the Court, to administer Claims for Benefits pursuant to the Settlement Agreement.
12. "Class Counsel Representative(s)" shall mean one or more individual members of the Class Counsel who are selected by the Class Counsel to represent the Class Counsel with respect to those matters specified in this Settlement Agreement.
13. "Class Representatives" shall mean Sheila Brown, Sharon Gaddie, Jose Gaddie, Vivian Naugle, Quentin Layer, Joan S. Layer, Joby Jackson-Reid and Harvey E. Reid, or such other or different persons as shall be designated by the Court as the representatives of the Settlement Class, in the action captioned *Sheila Brown, et al. v. American Home Products Corporation*, Civil Action No. 99-20593, pending in the United States District Court for the Eastern District of Pennsylvania.
14. "Common Benefit Attorneys" shall mean those attorneys who contributed to the creation of the Settlement Trust through work devoted to the "common benefit" of Class Members, including any attorney who reasonably believes that he or she actually conferred benefits upon the Class Members as a whole through state court litigation, subject to determination by the Court.
15. "Court" and/or "Trial Court" and/or "Federal District Court" means the United States District Court for the Eastern District of Pennsylvania presiding over MDL Docket No. 1203.
16. "Credit" has the meaning provided in Section VII.A.
17. "Cross-Claim Credit" has the meaning provided in Section VII.C.1.g.
18. "Date 1" is the date which is 210 days after Final Judicial Approval, by which (1) Class Members in Subclasses 1(a) and 1(b) must register to receive refund and/or Screening Program benefits from Fund A, and (2) Class Members in Subclasses 2(a) and 2(b) must register to receive refund benefits from Fund A.
19. "Date 2" is the date which is 120 days after the end of the Screening Period.
20. "Diet Drug(s)" shall mean Fenfluramine marketed under the brand name Pondimin<sup>®</sup> and/or Dexfenfluramine marketed under the brand name Redux<sup>™</sup>.
21. "Endocardial Fibrosis" is defined as a condition (a) diagnosed by (1) endomyocardial biopsy that demonstrates fibrosis and cardiac catheterization that demonstrates restrictive cardiomyopathy or (2)

autopsy that demonstrates endocardial fibrosis and (b) other causes, including dilated cardiomyopathy, myocardial infarction, amyloid, Loeffler's endocarditis, endomyocardial fibrosis as defined in Braunwald<sup>1</sup> (involving one or both ventricles, located in the inflow tracts of the ventricles, commonly involving the chordae tendineae, with partial obliteration of either ventricle commonly present), focal fibrosis secondary to valvular regurgitation (*e.g.*, "jet lesions"), focal fibrosis secondary to catheter instrumentation, and hypertrophic cardiomyopathy with septal fibrosis, have been excluded.

22. "FDA Positive" is defined as follows:

- a. With respect to a diagnosis based on an Echocardiogram conducted between the commencement of Diet Drug use and September 30, 1999, FDA Positive is a condition in which the Cardiologist interpreting the Echocardiogram, in the ordinary course of medical treatment, has issued a written report which clearly states that the individual has mild or greater regurgitation of the aortic valve and/or moderate or greater regurgitation of the mitral valve; provided however, that this definition shall be applicable only to qualification of a Diet Drug Recipient for Fund A benefits. In order to qualify for Matrix Compensation Benefits, a Diet Drug Recipient must present evidence that he or she had an Echocardiogram prior to the end of the Screening Period that meets the requirements of Section I.22.b below.
- b. With respect to a diagnosis based on an Echocardiogram conducted after September 30, 1999, FDA Positive is defined as mild or greater regurgitation of the aortic valve of the heart and/or moderate or greater regurgitation of the mitral valve of the heart as these levels are defined in Singh<sup>2</sup> (1999) and measured by an echocardiographic examination performed and evaluated by qualified medical personnel following the protocol as outlined in Feigenbaum<sup>3</sup> (1994) or Weyman<sup>4</sup> (1994).

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<sup>1</sup> *Heart Disease: A Textbook of Cardiovascular Medicine* 1433-34 (Eugene Braunwald, 5<sup>th</sup> ed. 1997) [hereinafter "Braunwald I"].

<sup>2</sup> J. P. Singh, et al., *Prevalence of Clinical Determinants of Mitral, Tricuspid and Aortic Regurgitation (The Framingham Heart Study)*, 83 Am. J. Cardiology 897, 898 (1999) [hereinafter "Singh"].

<sup>3</sup> Harvey Feigenbaum, *Echocardiography* 68-133 (5<sup>th</sup> ed. 1994) [hereinafter "Feigenbaum"].

<sup>4</sup> Arthur E. Weyman, *Principles and Practice of Echocardiography* 75-97 (2d ed. 1994) [hereinafter "Weyman"].

The degrees of regurgitation are determined as follows:

- Aortic Valve -- Mild or greater regurgitation, defined as regurgitant jet diameter in the parasternal long-axis view (or in the apical long-axis view, if the parasternal long-axis view is unavailable), equal to or greater than ten percent (10%) of the outflow tract diameter (JH/LVOTH).
- Mitral Valve -- Moderate or greater regurgitation, defined as regurgitant jet area in any apical view equal to or greater than twenty percent (20%) of the left atrial area (RJA/LAA).

23. "Final Judicial Approval" refers to the approval of the Settlement Agreement as a whole by the Federal District Court and such approval becoming final by the exhaustion of all appeals, if any, without substantial modification of the order or orders granting such approval. Final Judicial Approval shall be deemed not to have been obtained in the event that Trial Court Approval is denied, and the period for appealing such denial has expired without any such appeal having been taken.
24. "Final Judicial Approval Date" shall mean the date on which Final Judicial Approval occurs.
25. "Fiscal Year" shall mean the partial calendar year and each calendar year after the Final Judicial Approval Date as follows. The first Fiscal Year shall be the partial calendar year beginning on the Final Judicial Approval Date. The second Fiscal Year shall be the calendar year beginning on the first day of the year following the year in which the Final Judicial Approval Date occurs, and so forth. "Fiscal Quarter" shall mean the partial calendar quarter and each calendar quarter after the Final Judicial Approval Date as follows. The first Fiscal Quarter shall be the partial calendar quarter beginning on the Final Judicial Approval Date. The second Fiscal Quarter shall be the calendar quarter beginning on the first day of the calendar quarter following the quarter in which the Final Judicial Approval Date occurs, and so forth.
26. "Full Credit" has the meaning provided in Section VII.A.4.
27. "Fund A Amounts" has the meaning provided in Section III.B.1.
28. "Fund A Escrow Account" has the meaning provided in Section III.B.3.
29. "Fund B Amounts" has the meaning provided in Section III.C.1.
30. "Fund B Deposit Amount" has the meaning provided in Section III.C.3.
31. "Fund B Quarterly Notice" has the meaning provided in Section III.C.3.

32. "Initial Opt-Out Period" shall mean the period to be established by the Court during which Class Members may exercise the Initial Opt-Out right described in Section IV.D.2.
33. "Interim Claims Administrator(s)" shall mean the two persons mutually agreed upon by AHP and Class Counsel subject to approval by the Court pursuant to Section VI.A.2 to exercise all of the functions which are to be exercised by the Claims Administrator and/or the Trustees prior to approval of the Trustees.
34. "Interim Escrow Agent" shall mean the person or entity mutually agreed upon by AHP and Class Counsel subject to approval by the Court pursuant to Section VI.A.1 to receive, hold and disburse Fund A Amounts and Fund B Amounts until Court approval of the Trustees pursuant to Section VI.A.3 herein.
35. [This section intentionally left blank.]
36. "Judgment" has the meaning provided in Section VII.A.4.
37. "Matrix-Level Condition" shall mean a physiological condition with a level of severity meeting any of the criteria specified in Section IV.B.2.c.
38. "Mild Mitral Regurgitation" refers to mild mitral valve regurgitation as that level is defined in Singh<sup>5</sup> (1999) and measured by an echocardiographic examination performed and evaluated by qualified medical personnel following the protocol as outlined in Feigenbaum<sup>6</sup> (1994) or Weyman<sup>7</sup> (1994). That degree of regurgitation is determined as follows: (1) either the RJA/LAA ratio is more than five percent (5%) or the mitral regurgitant jet height is greater than 1 cm from the valve orifice, and (2) the RJA/LAA ratio is less than twenty percent (20%).
39. "Mitral Valve Prolapse" refers to a condition where (a) the echocardiogram video tape or disk includes the parasternal long axis view and (b) that echocardiographic view shows displacement of one or both mitral leaflets >2mm above the atrial-ventricular border during systole, and >5mm leaflet thickening during diastole, as determined by a Board-Certified Cardiologist.<sup>8</sup>

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<sup>5</sup> Singh, *supra* note 2.

<sup>6</sup> Feigenbaum, *supra* note 3.

<sup>7</sup> Weyman, *supra* note 4.

<sup>8</sup> See Lisa A. Freed, *et al.*, *Prevalence and Clinical Outcomes of Mitral Valve Prolapse*, 341 New Eng. J. Med. 1, 2 (1999) [hereinafter "Freed"].

40. "Non-AHP Released Parties" shall mean those Released Parties other than the AHP Released Parties.
41. "Nonpayment Hearing" has the meaning provided in Section III.E.6.a.
42. "Plaintiffs' Counsel" shall mean the Class Counsel and the Common Benefits Attorneys.
43. [This section intentionally left blank.]
44. "Preliminary Approval" shall mean the Federal District Court's conditional certification of the Settlement Class and preliminary approval of this Settlement Agreement pursuant to Fed. R. Civ. P. 23(a), 23(b)(2), 23(b)(3), 23(c)(1) and 23(e) and entry of an order or orders providing for issuance of notice to the Settlement Class.
45. "Preliminary Approval Date" shall mean the date on which Preliminary Approval occurs.
46. "Primary Pulmonary Hypertension" ("PPH") is defined as either or both of the following:
  - a. For a diagnosis based on examinations and clinical findings prior to death:
    - (1) (a) Mean pulmonary artery pressure by cardiac catheterization of  $\geq 25$  mm Hg at rest or  $\geq 30$  mm Hg with exercise with a normal pulmonary artery wedge pressure  $\leq 15$  mm Hg<sup>9</sup>; or
    - (b) A peak systolic pulmonary artery pressure of  $\geq 60$  mm Hg at rest measured by Doppler echocardiogram utilizing standard procedures; or
    - (c) Administration of Flolan to the patient based on a diagnosis of PPH with cardiac catheterization not done due to increased risk in the face of severe right heart dysfunction; and
    - (2) Medical records which demonstrate that the following conditions have been excluded by the following results<sup>10</sup>:

<sup>9</sup> See L. J. Rubin & S. Rich, 99 *Primary Pulmonary Hypertension* (1997) [hereinafter "Rubin & Rich"].

<sup>10</sup> See Eugene Braunwald, *Essential Atlas of Heart Diseases*, Current Med. For Atty's 10-9 (1997) [hereinafter "Braunwald II"].

- (a) Echocardiogram demonstrating no primary cardiac disease including, but not limited to, shunts, valvular disease (other than tricuspid or pulmonary valvular insufficiency as a result of PPH or trivial, clinically insignificant left-sided valvular regurgitation), and congenital heart disease (other than patent foramen ovale); and
  - (b) Left ventricular dysfunction defined as LVEF < 40% defined by MUGA, Echocardiogram or cardiac catheterization; and
  - (c) Pulmonary function tests demonstrating the absence of obstructive lung disease ( $FEV_1/FVC > 50\%$  of predicted) and the absence of greater than mild restrictive lung disease (total lung capacity > 60% of predicted at rest); and
  - (d) Perfusion lung scan ruling out pulmonary embolism; and
  - (e) If, but only if, the lung scan is indeterminate or high probability, a pulmonary angiogram or a high resolution angio computed tomography scan demonstrating absence of thromboembolic disease; and
- (3) Conditions known to cause pulmonary hypertension<sup>11,12,13</sup> including connective tissue disease known to be causally related to pulmonary hypertension, toxin induced lung disease known to be causally related to pulmonary hypertension, portal hypertension, significant obstructive sleep apnea, interstitial fibrosis (such as silicosis, asbestosis, and granulomatous disease) defined as greater than mild patchy interstitial lung disease, and familial causes, have been ruled out by a Board-Certified Cardiologist or Board-Certified Pulmonologist as the cause of the person's pulmonary hypertension.

-OR-

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<sup>11</sup> See Rubin & Rich, *supra* note 9.

<sup>12</sup> See Braunwald I, *supra* note 1 at 796-798.

<sup>13</sup> Stuart Rich, *Executive Summary from the Symposium on Primary Pulmonary Hypertension, Evian, France, co-sponsored by the World Health Organization, September 6-10, 1998*, <<http://www.who.int/ncd/cvd/pph.html>>

- b. For a diagnosis made after the individual's death:
  - (1) Autopsy demonstrating histopathologic changes in the lung consistent with primary pulmonary hypertension and no evidence of congenital heart disease (other than a patent foramen ovale) with left-to-right shunt, such as ventricular septal defect as documented by a Board-Certified Pathologist; and
  - (2) Medical records which show no evidence of alternative causes as described above for living persons.

This definition of PPH ("the PPH Definition") is intended solely for the purpose of describing claims excluded from the definition of Settled Claims and for purposes of Section VII.B.4 and 5, below. The Parties agree that the PPH Definition includes but is broader than the rare and serious medical condition suffered by the individuals described in L. Abenhaim, *et al.*, *Appetite-Suppressant Drugs and the Risk of Primary Pulmonary Hypertension*, *International Primary Pulmonary Hypertension Study Group*, 335(9), *New England Journal of Medicine*, 609-16 (1996) (the "IPPHS study"). The subjects in that study exhibited significantly elevated pulmonary artery pressures with an average systolic pulmonary artery pressure of 88 mm Hg and average mean pulmonary artery pressure of 57 mm Hg. Two-thirds of the IPPHS patients demonstrated NYHA Class III or IV symptoms. While the IPPHS subjects would fall within the PPH Definition, the definition also includes persons with a milder, less serious medical condition.

- 47. "Qualified Physician" shall mean a Board-Certified or Board-Eligible Cardiologist.
- 48. "Released Parties" shall mean:
  - a. AHP and each of its subsidiaries, affiliates, and divisions, including, but not limited to, Wyeth-Ayerst Laboratories Division, Wyeth-Ayerst Laboratories Co., Wyeth-Ayerst Pharmaceuticals Inc., and American Cyanamid Corporation, along with each of their respective current and former officers, directors, employees, attorneys, agents, and insurers;
  - b. Any and all predecessors, successors, and/or shareholders of AHP and each of its subsidiaries, affiliates, and divisions; provided, however, that any such person or entity shall be considered a Released Party only to the extent that such person or entity is sued in its capacity as a predecessor, successor, and/or shareholder of AHP or its subsidiaries, affiliates, and divisions;

- c. Any and all suppliers of materials, components, and services used in the manufacture of Pondimin<sup>®</sup> and/or Redux<sup>™</sup>, including the labeling and packaging thereof, along with each such person's or entity's predecessors, successors, parents, subsidiaries, affiliates, and divisions, and each of their respective current and former shareholders, officers, directors, employees, attorneys, agents, and insurers; provided, however, that no person or entity described in this subsection shall be a Released Party with respect to any claims based upon his, her or its own independent negligence or culpable conduct;
- d. All distributors of Pondimin<sup>®</sup> and/or Redux<sup>™</sup>, including wholesale distributors, private label distributors, retail distributors, hospitals and clinics, and their respective predecessors, successors, parents, subsidiaries, affiliates, and divisions, and their respective current and former shareholders, officers, directors, employees, attorneys, agents, and insurers; provided that: (1) such persons and entities described in this section shall be a Released Party only as to claims as to which such persons would have a statutory or common-law right of indemnity against AHP; (2) no person or entity described in this section shall be a Released Party to the extent that any claim is based upon his, her or its own independent negligence or culpable conduct, including, without limitation, negligence or professional malpractice asserted against hospitals, clinics, and diet centers; and (3) no person or entity described in this section shall be a Released Party with respect to the manufacture, sale, or distribution of any Phentermine hydrochloride or Phentermine resin pharmaceutical product.
- e. All physicians who prescribed, and all pharmacists and pharmacies who dispensed, Pondimin<sup>®</sup> and/or Redux<sup>™</sup> to the extent that liability against such physicians, pharmacists or pharmacies is based on:
  - (1) the prescription or dispensing of Pondimin<sup>®</sup> and/or Redux<sup>™</sup> in a manner consistent with the product labeling; and/or
  - (2) the prescription or dispensing of Pondimin<sup>®</sup> for any period longer than a "few weeks"; and/or
  - (3) the prescription or dispensing of Pondimin<sup>®</sup> and/or Redux<sup>™</sup> for concomitant use with Phentermine hydrochloride or Phentermine resin; and/or
  - (4) a claim that the physician's or pharmacist's liability stems solely from having prescribed or dispensed Pondimin<sup>®</sup> and/or Redux<sup>™</sup>; and/or